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Elizabeth A. Mazzio 982 West Brevard Street, D #22 Tallahassee, FL 32304				
		EXAMINER FLOOD, MICHELE C		
		ART UNIT PAPER NUMBER 1655		
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

10/801,520

Applicant(s)

MAZZIO ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-63 is/are pending in the application.
- 4a) Of the above claim(s) 60-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on December 1, 2006 with the cancellation of Claims 1-32 and the addition of newly submitted Claims 33-63.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted Claims 60-63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the subject matter of newly submitted Claims 60-63 is directed to a method of treating ski diseases comprising the topical administration of a composition comprising claim-designated ingredients; and the oral administration of vitamin B3, whereas the subject matter of originally elected Claims 1-16 was directed to a topical skin composition comprising a safe and effective amount of: a) one or more active ingredients selected from the group consisting of wormwood (species *Artemisia absinthium* or genus *Artemisia*), black walnut (*Juglans nigra* or genus *Juglans*), niacin (niacinamide, nicotinic acid and chemical derivatives of niacin); b) Aloe vera or a dermatologically acceptable carrier; c) one or more active ingredients selected from the group consisting of garlic (*Allium sativum* or genus *Allium*), turmeric (*Curcuma longa* or genus *Curcuma*), propolis, St. John's wort (*Hypericum perforatum* or genus *Hypericum*), licorice (*Glycyrrhiza glabra* or genus *Glycyrrhiza*), chamomile (*Matricaria chamomile* or genus *Matricaria* or genus

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Artemisia) and herbal anti-bacterial agents. Applicant is reminded that in the reply filed on September 14, 2004 Applicant elected Group I, Claims 1-7 drawn to a composition, without traverse; and, Claims 17-21 drawn to a method were withdrawn from further consideration as a group drawn to a non-elected invention. Moreover, the method claims of Claims 60-63 are drawn to a method of treating skin diseases that requires both the oral administration and topical administration of ingredients not required by the composition claims of newly submitted Claims 33-59.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 60-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 33-59 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-59 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "garlic alone in combination with propolis" in Claim 33, line 5. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on December 1, 2006 now recite a topical skin care composition useful for treating dyshidrosis (pompholyx) and dry skin disorders, said composition comprising a therapeutically effective amount of a) black walnut and/or wormwood; b) turmeric; c) garlic alone or in combination with propolis; d) two or more antibacterial/anti-inflammatory herbs selected from the group consisting of St. John's wort, licorice, chamomile, clove, nutmeg, ginger frankincense and myrrh; e) Aloe vera alone or in combination with a dermatologically acceptable carrier, and f) optionally niacin. However, the specification as originally filed provides only for compositions comprising propolis as an optional ingredient. For example, at [00019] in the specification as originally filed Applicant discloses use of propolis as a substitute to replace ingredients that may otherwise cause allergic skin reactions such as garlic in the making of the instantly claimed composition. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concept for a topical skin care composition comprising garlic in combination with garlic, with regard to Claim 33. There is only one exemplified composition comprising a) black walnut and/or wormwood; b) turmeric; c) garlic alone; d) two or more antibacterial/anti-inflammatory herbs selected from the group consisting of St. John's wort, licorice, chamomile, clove, nutmeg, ginger frankincense and myrrh; e) Aloe vera alone or in combination with a dermatologically acceptable carrier, and f) optionally niacin. This is not sufficient support for the new aforementioned genera. This

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is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 47, 48 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Claim 47, line 9, recites the abbreviation "EDTA". Applicant can overcome the rejection by replacing "EDTA" with ethylenediaminetetra acetic acid.

The metes and bounds of Claim 48 are rendered indefinite because niacin is defined as a constituent selected from a Markush group containing compounds other niacin. Thus, it is unclear as to the subject matter to which Applicant seeks patent

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protection since niacin can not be defined as a compound other than itself. The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 35-38, 41, 42, 44-47, 50-52, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao-fan et al. (U) in view of Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559), and Scivoletto (AA1, US 6,248,763 B1). Newly applied as necessitated by amendment.

Applicant claims a topical skin care composition useful for treating dyshidrosis (pompholyx) and dry skin disorders, said composition comprising a therapeutically effective amount of a) black walnut and/or wormwood; b) turmeric; c) garlic alone or in combination with propolis; d) two or more antibacterial/anti-inflammatory herbs selected from the group consisting of St. John's wort, licorice, chamomile, clove, nutmeg, ginger

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frankincense and myrrh; e) Aloe vera alone or in combination with a dermatologically acceptable carrier, and f) optionally niacin.

Xiao-fan teaches a topical skin care composition useful for the treatment of dry skin disorders (neurodermatitis) comprising: a) wormwood (Folium Artemisiae argyrii or *Artemisia argyrii*, 6 grams); c) garlic (Bulbus Allii Sativi or *Allium sativum*, 2 heads); d) ginger (Rhizoma Zingiberis Officinalis or *Zingiber officinale*, 50 grams) and chamomile (Folium Camelliae Theae or *Matricaria chamomile*, 6 grams), on pages 136-137 under "Mugwort & Ginger Tea".

The teachings of Xiao-fan are set forth above. Xiao-fan teaches the instantly claimed composition except for the claim-designated ingredients of turmeric and aloe. However, it would have been obvious to one ordinary skill in the art to add the instantly claimed ingredients to the composition taught by Xiao-fan to provide the instantly claimed invention because at the time the invention was made turmeric and aloe were known in the art of herbal medicine as being useful in the making of topical skin compositions useful for the treatment of dry skin disorders, as evidenced by the teachings of Hidaka, Yuuma and Scivoletto. Firstly, Hidaka teaches a topical skin care composition useful for the treatment of dry skin disorders comprising a therapeutically effective amount of turmeric obtained from *Curcuma longa* and a vegetable oil such as sesame oil, olive oil, jojoba oil or camellia oil and other dermatologically acceptable carrier such as antioxidants (licorice extract, clove extract, propolis extract), phospholipids, palmitic acid, glycerides, etc. See [0002] through [0019]. At [0020], Hidaka teaches that the total weight amount of turmeric comprising the referenced

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composition is 0.5% - 20% of the total weight of the composition. In another example, Yuuma teaches a topical skin care composition useful for the treatment of dry skin disorders comprising a therapeutically effective amount of turmeric (0.01% - 20 weight % based on the whole composition) and a pharmaceutically acceptable carrier, such as antioxidants, carboxylic acids, para-aminobenzoic acid (PABA), thickeners, gums, starch, talc, titanium dioxide, gelatin, and the like. See [0001] to [000033]. The composition taught by Yuuma can be in the form of a lotion, a capsule, aerosol, cream, and a liquid. See [0038]. Secondly, Scivoletto teaches a skin care composition comprising therapeutically effective amounts of *Aloe vera* (35% to 45%), niacin (0.01 % to 1%) and a pharmaceutically acceptable carrier (for example, chamomile, glycerin, methylparaben, propylparaben, imidazolidinyl urea, guanine, mineral oil, myristyl myristate, etc.), which is useful in the treatment of dry skin disorders in the form of a makeup, lipstick, lotion or foot bath, scalp wash or cleanser. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the turmeric taught by either Hidaka or Yuuma; and, the aloe and niacin composition taught by Scivoletto to the composition taught by Xiao-fan to provide the instantly claimed composition because Hidaka teaches that compositions comprising therapeutically effective amounts of turmeric obtained from *Curcuma longa* are useful in the treatment of eczema, psoriasis, xerosis, atopic dermatitis, xerosis, asteatosis, dryness athlete's foot and chapped skin taught, at [0023]; Yuuma teaches that the referenced skin care composition comprising therapeutically effective amounts of turmeric was useful in the treatment of dry skin

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disorders, inflammatory skin diseases, and skin disorders characterized by itching and was useful in reducing skin desquamation and improving skin appearance; and, Scivoletto teaches that the referenced composition comprising aloe vera, niacin and pharmaceutically acceptable carrier is useful for the treatment of psoriasis, athlete's foot, eczema, and skin conditions associated with itching.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Claims 33-38, 41, 42, 44-47, 49-52, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of in view of Engel et al. (B*), Wixforth (C*), Rosen (D*) and Laforet (E*). Newly applied as necessitated by amendment.

The composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto are set forth above. The combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto teach the instantly claimed composition except for the claim-designated ingredient of black walnut. However, it would have been obvious to one ordinary skill in the art to add the instantly claimed ingredient to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because at the time the invention was made black walnut as well as plants extracts derived from the genus *Juglans* were known in the art of herbal medicine as being useful in the making of skin care compositions, as evidenced by the teachings of Engel, Wixforth, Rosen and Laforet. For example, Engel teaches a composition comprising an extract derived from black walnut, namely 40% of black walnut oil, which is useful in moisturizing dry skin; Rosen teaches a composition comprising juglones, such as 5-hydroxy-1,4-naphthoquinone, which is useful in the treatment of dermatitis and itching disorders derived from plants of the genus *Juglans*; Wixforth teaches extracting 5-hydroxy-1,4-naphthoquinone from *Juglans nigra* having germicidal properties that is used in the making of topical cosmetic preparations, such as foot powders.; and, Laforet teaches a composition comprising therapeutically amounts of an

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extract of *Juglans regia* which is useful in the making of topical skin care compositions having anti-inflammatory activity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either black walnut or a plant extract derived from the genus *Juglans* to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because each of Engel, Wixforth, Rosen and Laforet taught that that the claim-designated ingredients were useful in the making of topical skin care compositions due to their anti-dermatitis, anti-itching, antibacterial, anti-inflammatory properties, anti-collagenase, anti-elastase, and anti-apoptotic, as well as moisturizing effect.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been

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routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 33, 35-39, 41, 42, 44-47, 50-53, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559), and Scivoletto (AA1, US 6,248,763 B1) in view of Otsuka et al. (RR, JP 10-175878). Newly applied as necessitated by amendment.

The composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto are set forth above. The combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto teach the instantly claimed composition except for the claim-designated ingredient of garlic combined with propolis. However, it would have been obvious to one ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because Otsuka taught a composition comprising garlic in combination with propolis in an amount of 10% of the total weight of the composition that was useful for the treatment of skin disorders. The composition taught by Otsuka is in the form of a liquid for bathing or tablet; and comprises deodorized garlic. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the composition

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containing pyroligneous acid, chitin, chitosan, garlic and propolis taught by Otsuka to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because Otsuka teaches that the referenced composition is useful in treating not only parasitic skin diseases but also atopic dermatitis, athlete's foot, scabies, and skin diseases characterized by symptoms of dryness and itching, at [0011].

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 33-38, 41, 42, 44-47, 49-52, 54, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of in view of Koch et al. (SS, DE 10131641) and Nishibe et al. (TT, JP 09-157176). Newly applied as necessitated by amendment.

The composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto are set forth above. The combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto teach the instantly claimed composition except for the claim-designated ingredients of *Hypericum perforatum* or an extract derived from the plant genus *Hypericum*. However, it would have been obvious to one ordinary skill in the art to add the instantly claimed ingredient to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because at the time the invention was made *Hypericum perforatum* or an extract derived from the plant genus *Hypericum* were known in the art of herbal medicine as being useful in the making of topical skin care compositions due to their skin health promoting functional effects, as evidenced by the teachings of Koch and Nishibe. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ingredients

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taught by either Koch or Nishibe to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because Koch teaches that *Hypericum perforatum* extract is useful in making compositions for topical administration for treating psoriasis; and, Nishibe teaches adding therapeutically effective amounts of *Hypericum erectum* extract is useful in making topical skin care preparations for the treatment of atopic dermatitic diseases or skin roughening diseases or sensitive skin, and skin inflammation disorders in various conventional pharmaceutical forms (liquid, lotion, cream, ointment, gel, powder, capsule, tablet, shampoos, and the like).

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been

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routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 33-38, 41-47, 49-52 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of Bombardelli et al. (A*). Newly applied as necessitated by amendment.

The composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto are set forth above. The combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto teach the instantly claimed composition except for the claim-designated ingredient of *Commiphora molmol*. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the composition taught by the combined teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention because at the time the invention was made Bombardelli taught a topical skin care composition comprising *Commiphora mukul* that was useful in the treatment of inflammatory skin diseases and dermatitis. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the *Commiphora mukul* taught by Bombardelli to the composition taught by the combined teachings of Xiao-fan, Hidaka,

Yuuma and Scivoletto to provide the instantly claimed composition because Bombardelli teaches that therapeutically effective amounts of the claim-designated ingredient improves dermatological affections, such as atopic dermatitis and stimulates cycatrization.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 16, 2007